#### SANDIA REPORT

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# Sandia National Laboratories Advanced Simulation and Computing (ASC) Software Quality Plan Part 2: Mappings for the ASC Software Quality Engineering Practices Version 1.0

Edward A. Boucheron, Richard R. Drake, H. Carter Edwards, Molly A. Ellis, Christi A. Forsythe, Robert Heaphy, Ann L. Hodges, Constantine Pavlakos, Joseph R. Schofield, Judy E. Sturtevant and C. Michael Williamson

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# Sandia National Laboratories Advanced Simulation and Computing (ASC) Software Quality Plan

# Part 2: Mappings for the ASC Software Quality Engineering Practices

#### Version 1.0

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#### Abstract

The purpose of the Sandia National Laboratories Advanced Simulation and Computing (ASC) Software Quality Plan is to clearly identify the practices that are the basis for continually improving the quality of ASC software products. The plan defines the ASC program software quality practices and provides mappings of these practices to Sandia Corporate Requirements CPR 1.3.2 and 1.3.6 and to a Department of Energy document, *ASCI Software Quality Engineering: Goals, Principles, and Guidelines*. This document also identifies ASC management and software project teams' responsibilities in implementing the software quality practices and in assessing progress towards achieving their software quality goals.

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#### 1 Introduction

This document, *Part 2: Mappings for the ASC Software Quality Engineering Practices*, contains the mappings for the practices and artifacts found in *Part 1: Practices* of the *Sandia National Laboratories Advanced Simulation and Computing (ASC) Software Quality Plan* (Software Quality Plan). The purpose of the mappings contained herein is to provide requirements traceability from the Software Quality Plan to the driver documents as well as to two additional ASC program and industry standards requested by the ASC Quality Management Council (AQMC). Figure 1 illustrates the relationship between the software quality plan and the standards and guidelines that are mapped in this document.

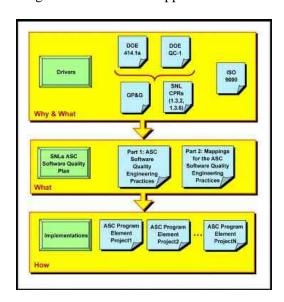


Figure 1. Relationship Between Software Quality Plan and Mapping Documents.

In all mappings provided, practice numbers or sections of Part 1 of the Software Quality Plan are listed to indicate a mapping to a particular requirement. Gaps between the various requirements and the Software Quality Plan are indicated in a light red color. An "N/A" is used where a particular requirement appears non-applicable. No degree of conformance is denoted or implied to the various requirements by the mappings. The practitioner or reader should not interpret indicated mappings to guarantee compliance.

This document is organized as follows:

- Section 1: Introduction
- Section 2: ASC Software Quality Plan Practices and Artifacts Tables
- Section 3: Mappings to the *Department of Energy, DOE/AL Quality Criteria (QC-1)*, Revision 10, February 2004.
- Section 4: Mappings to the ASCI Software Quality Engineering: Goals, Principles, and Guidelines (GP&G),
- Section 5: Mappings to the SNL Corporate Process Reports
  - Section 5.1: CPR001.3.2, Corporate Quality Assurance Program (August 2003)
  - Section 5.2: CPR001.3.6, Corporate Software Quality Assurance (December 2001)
- Section 6: Mappings to the *ISO 9001:2000 Quality Management Systems Requirements*, International Standards Organization, December 2000.

## 2 ASC Software Quality Plan Practices and Artifacts

The following tables provide lists of the practices and artifacts stated in *Part 1: Practices* of the Software Quality Plan.

Practice Number	Description of Software Quality Plan Practices
PR1	Document and maintain a strategic plan.
PR2	Perform a risk-based assessment, determine level of formality and applicable practices, and obtain approvals.
PR3	Document lifecycle processes and their interdependences, and obtain approvals.
PR4	Define, collect, and monitor appropriate process metrics.
PR5	Periodically evaluate quality problems and implement process improvements.
PR6	Identify stakeholders and other requirements sources.
PR7	Gather and manage stakeholders' expectations and requirements.
PR8	Derive, negotiate, manage, and trace requirements.
PR9	Identify and analyze risk events.
PR10	Define, monitor, and implement the risk response.
PR11	Create and manage the project plan.
PR12	Track project performance versus project plan and implement needed (corrective) actions.
PR13	Communicate and review design.
PR14	Create required software and product documentation.
PR15	Identify and track third party software products and follow applicable agreements.
PR16	Identify, accept ownership, and manage assimilation of other software products.
PR17	Perform version control of identified software product artifacts.
PR18	Record and track issues associated with the software product.
PR19	Ensure backup and disaster recovery of software product artifacts.
PR20	Plan and generate the release package.
PR21	Certify that the software product (code and its related artifacts) is ready for release and distribution.
PR22	Distribute release to customers.
PR23	Define and implement a customer support plan.
PR24	Implement the training identified in the customer support plan.
PR25	Evaluate customer feedback to determine customer satisfaction.
PR26	Develop and maintain a software verification plan.
PR27	Conduct tests to demonstrate that acceptance criteria are met and to ensure that previously
	tested capabilities continue to perform as expected.
PR28	Conduct independent technical reviews to evaluate adequacy with respect to requirements.
PR29	Determine project team training needs to fulfill assigned roles and responsibilities.
PR30	Track training undertaken by project team.

Artifact Number	Description of Software Quality Plan Artifacts
AR1	Strategic plan: [project's mission, management, stakeholders]
AR2	Approved level of formality and applicable practices
AR3	Approved project processes
AR4	Process and product metrics
AR5	Project process improvement actions
AR6	Product expectations and requirements
AR7	Software requirements and attributes
AR8	List of stakeholders and organizational commitments
AR9	Project plan: [risks events, risk plan, overview, milestones, task list, resource information,
	roles and responsibility assignments, assumptions, constraints, dependencies, budget,
A D10	schedule, SCM plan, etc.]
AR10	Project reviews and needed (corrective) actions: [risk responses, tracking and oversight responses]
AR11	Design artifacts: [documentation and/or reviews]
AR12	Implementation artifacts: [software code, assimilated other software, design documents, user
11112	documentation, developer's guide, installation guide, theory manual, interface manual, etc.]
AR13	Identification and acquisition records
AR14	Version controlled records, including baselines and associated configurations
AR15	Backup records and recovery test results
AR16	Managed issues: [product quality results (for example, non-conformances), enhancements,
	defects, questions, inquiries]
AR17	Release specification
AR18	Product release package (bill of materials, release notes, certification, software, etc.)
AR19	Customer support plan including training
AR20	Customer training records
AR21	Customer satisfaction evaluation
AR22	Software verification plan
AR23	Test artifacts: [test cases, test results]
AR24	Technical reviews (evidence that review occurred and review results)
AR25	Project team training needs
AR26	Project team training records

## **3** DOE/AL QC-1 Revision 10 Mappings

The following table maps the requirements of the DOE QC-1 (sections 2.1 through 4.1) to the ASC Software Quality Plan.

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
2.1	Risk-Based Program	To have a cohesive, effective and integrated quality management system, a risk-based approach must be used to determine the extent (tailoring) of application of QC-1 requirements.	PR1, PR2
2.1		An organization shall use a risk management process when choosing to apply the "shall" requirements of this document in a graded (tailored) manner and document that process in their QAP or WQAP.	PR1, PR2
2.1		Factors that may be considered in the risk management process for graded application include a. the consequences of malfunction or failure of an item,	PR1, PR2
2.1		b. the inappropriate use of the results of services provided,	PR1, PR2
2.1		c. the probability of the occurrence of the postulated consequences,	PR1, PR2
2.1		d. the design and fabrication complexity of an item or difficulty of performing the service,	PR1, PR2
2.1		e. the need for special controls and oversight of processes, equipment, and performance,	PR1, PR2
2.1		f. the degree to which functional compliance can be demonstrated by inspection, test, or performance verification,	PR1, PR2, PR26, PR27, PR28
2.1		g. the quality history and degree of standardization of an item or service, and	PR1, PR2
2.1		h. the difficulty of repair, replacement, or replication of an item or service.	PR1, PR2
2.2	Quality Management Program	NNSA and its contractors shall integrate quality principles with risk-based analysis into management and work practices at all levels so that missions are accomplished and customer requirements are met.	PR1, PR2, PR9, PR10
2.2		Organizations shall integrate quality management into all facets of work planning and execution.	Software Quality Plan
2.2		A written QAP or WQAP shall be developed, implemented, and maintained that meets the requirements of this document.	Software Quality Plan
2.2		The QAP or WQAP shall a. describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work;	Tables 1 & 2, PR1, PR11
2.2		b. identify the organization's senior management positions;	Table 1, PR1
2.2		c. identify QC-1 requirements and other weapon quality requirements contained in contractual documents and their flow down to implementing procedures;	Figure 1, Appendix C, Appendix G, CPR1.3.2, CPR 1.3.6
2.2		d. state the justification for graded (tailored) application of QC-1 requirements (if any); and	Appendix C, Appendix G, Figure 1, PR1, PR2
2.2		e. describe management processes, including planning, scheduling, and resource considerations.	Table 1, PR1, PR11

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
2.2.1	Submittal, Approval, Implementation and Reporting	NNSA and its contractors responsible for work in any weapon life-cycle phase shall a. submit a QAP or WQAP and implementation plan for achieving full compliance to requirements where not presently in compliance to the appropriate NNSA approval authority,	Software Quality Plan
2.2.1		b. follow the submitted QAP or WQAP and implementation plan, pending response from the NNSA approval authority;	Table 1, PR1, PR11
2.2.1		c. submit any significant changes to the QAP or WQAP and any associated implementation plan for approval and describe how the changes continue to satisfy the quality requirements;	Table 1, PR1, PR11
2.2.1		d. conduct work in accordance with the approved QAP or WQAP and implementation plan;	Software Quality Plan
2.2.1		e. report quality management system and weapon activity metrics annually and on request to provide objective evidence of performance; and	Software Quality Plan
2.2.1		f. provide a management self-assessment report on performance to the QAP or WQAP annually.	Software Quality Plan
2.2.1		The approved organization QAP or WQAP and any associated implementation plan will be the basis for assessment of the organization's weapon quality program.	Software Quality Plan
2.3	Organization	There shall be a process to establish and document the organization structure, functional responsibilities, levels of authority, and lines of communication.	see NWSMU or ASC Organizational structure, Table 1, PR1
2.3		Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.	see NWSMU or ASC Organizational structure, Table 1, PR1, PR6
2.3		The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.	see NWSMU or ASC Organizational structure, Table 1, PR1, PR6, PR11
2.3		Personnel verifying quality achievement shall not be directly responsible for performing the work being evaluated and shall have the authority, direct access to management, organizational freedom, and access to work to perform their function.	PR1, section 4.4 Overview Description, PR28
2.4	Early and Continuous Application of Quality Principles	The organization responsible for any product or process design shall ensure that operating, production, and quality requirements are incorporated in the design process as early as feasible.	PR13
2.4		The design process shall provide for the timely identification and evaluation of key elements that are critical to program success and shall provide an objective means to measure design, product, process, and production readiness.	PR1, PR6, PR7, PR8, PR11, PR13, PR29
2.4		Producibility shall be formally addressed in the design and design change processes.	PR13
2.4		The design authority and production organization shall establish and document a process for evaluating producibility.	PR3, PR21
2.4		This process shall require the design and	N/A
2.5	Establishing and Validating Requirements	Beginning with development and continuing throughout the life cycle of the activity, processes shall be in place to identify, document, validate, control and maintain customer requirements.	PR3, PR6, PR7, PR8, PR13, PR17, PR18, PR20, PR23, PR26

QC-1 Section Number	QC-1 Section Title	QC-1 Requirements	ASC Software Quality Plan
2.5		Each organization shall document their process, including roles, responsibilities, and interfaces.	PR1, PR3, PR11
2.6	Planning	A risk management process shall be used to determine the extent of formal planning (including quality plans) that is required for development, programs, projects, processes, activities, materials, products, services, functions, product and stockpile certification, or organizational entities	section 4, PR1, PR2, PR9, PR10
2.6		NNSA shall address quality requirements in	N/A
2.7	Metrics	Each organization shall identify, track, trend, and report metrics and utilize them for corrective action and continuous improvement.	PR3, PR4, PR5
3.0	Quality		
3.1	Requirements		
3.1.1	Continuous Improvement	Processes to detect and prevent quality problems shall be established and implemented.	PR3, PR4, PR5
3.1.1	Process	Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected.	PR3, PR4, PR5
3.1.1		Correction shall include identifying the causes of problems and working to prevent recurrence.	PR3, PR4, PR5
3.1.1		Item characteristics, process implementation, and other quality related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement.	PR3, PR4, PR5
3.1.2	Prevention Versus Detection	The objective of a quality management system is to prevent errors and nonconformance, reduce variability, and build quality into products and processes.	section 4.2.3, PR3, PR4, PR5
3.1.2		Fundamental methods such as design of experiments, prototyping, process capability studies, Pareto analyses, and statistical process controls may be used to a. characterize processes,	PR3, PR4, PR5, Appendix F
3.1.2		b. simplify processes,	PR3, PR4, PR5, Appendix F
3.1.2		c. mistake-proof processes,	PR3, PR4, PR5, Appendix F
3.1.2		d. continually reduce product and process variability,	PR3, PR4, PR5, Appendix F
3.1.2		e. identify and minimize the number of unstable or error prone processes, and	PR3, PR4, PR5, Appendix F
3.1.2		f. provide early feedback of engineering and manufacturing data to determine the need for product or process changes.	PR3, PR4, PR5, Appendix F
3.1.3	Quality Cost Management	Quality cost management shall be applied to weapon activities throughout the entire weapon program life cycle.	PR1, PR3, PR11
3.1.3		A method for identifying, recording, and reporting the quality costs shall be established and documented in formal procedures.	PR3, PR11
3.1.3		These costs include but are not limited to cost of prevention, cost of appraisal, cost of internal failure, and cost of external failure.	PR3, PR11

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
3.1.3		The cost of nonconformance plus the cost of conformance	PR11, PR4
		and/or other appropriate cost metrics shall be utilized for performance measurement, problem identification, and	
		problem prevention.	
3.2	Training	Personnel shall be trained and qualified to ensure they are	PR11, PR29, PR30
	_	capable of performing their assigned work.	
3.2		Personnel shall be provided continuing training to ensure that job proficiency is maintained.	PR11, PR29, PR30
3.2		Evidence of training, qualification, and certification shall be	PR11, PR30
3.2		maintained.	PR11, PR29, PR30
3.2		Training is conducted to help ensure that personnel are competent to perform the assigned work to the quality required.	PK11, PK29, PK30
3.2		Competency is based on a combination of factors including	PR11, PR29, PR30
		education, training, skills and experience.	
3.2		Processes are required to ensure that personnel have	PR11, PR29, PR30
		appropriate and adequate experience, education, skills and	
		training, i.e., ensure the use of competent personnel for	
3.2		assigned work.  Highly qualified and motivated personnel, who are engaged,	PR1, PR11, PR29, PR30
3.2		should be the goal of any training program.	1111, 11111, 11122, 11100
3.3	Design	The design authority shall be responsible for the design of	PR1, PR11, PR13
	8	items and processes under its responsibility.	
3.3		Procedures shall be established and maintained to define and	PR1, PR3, PR11, PR13,
		control the design process, including design-related	PR18
2.2.1		development.	DD4 DD4 DD7 DD0 DD14
3.3.1	<b>Design Input</b>	Design inputs (customer requirements, etc.) shall be identified and documented, and their selection reviewed and approved	PR3, PR6, PR7, PR8, PR13
		prior to the final design implementation.	
3.3.2	Design Process	Items and processes shall be designed using sound	PR3, PR13
	_	engineering/scientific principles and appropriate standards.	
3.3.2		Designs shall provide a clear link between design inputs and	PR3, PR6, PR7, PR8, PR13
		design requirements, including production requirements and	
3.3.2		specifications.  Design work, including changes, shall incorporate applicable	PR6, PR7, PR8, PR13,
		requirements and design bases.	PR17, PR18
3.3.2		Designs shall also incorporate critical characteristics required	PR13
		for function, reliability, interchangeability, design life, safety, and dismantlement.	
3.3.2		Design requirements shall not be more restrictive than essential	PR13
0.0.2		for achieving required performance with appropriate margin.	
3.3.2		The design authority shall determine and set the value and	PR13
		tolerance for design specifications.	
3.3.2		The design authority should produce designs that minimize the	PR13
		opportunity for incorrect manufacture, assembly, use, or	
2 2 2		operation.	DD0 DD10 DD12 DD26
3.3.2		Calculations, modeling, and testing shall establish the design parameters and maintain the appropriate margins by taking into	PR9, PR10, PR13, PR26, PR27
		account uncertainties associated with the design envelope.	
3.3.2		Test equipment and instrumentation used	N/A
3.3.2		Design information that supports the disposition	N/A
3.3.2		2 30.5.1 morniadon diat supporto dio disposition	_ " - "

QC-1 Section Number	QC-1 Section Title	QC-1 Requirements	ASC Software Quality Plan
3.3.3	Design Verification	The adequacy of designs shall be verified and documented before approval and implementation.	PR13, PR26, PR27, PR28
	Design Reviews	Design reviews shall be conducted by individuals or groups other than those who performed the work to ensure, at the time of the review, that a. design inputs are complete and correct;	PR13, PR26, PR28
		b. assumptions necessary to perform the design are adequately described and valid;	PR8,PR9, PR10, PR13,
		c. applicable design standards are used;	PR13, PR28
		d. computer programs, including mathematical models used in simulation codes, are adequately verified and validated and recorded for future retrieval;	PR26, PR27, PR28
		e. suitable materials, parts, processes, and inspection and testing criteria are specified; and	PR26, PR27, PR28
		f. design qualification methods are adequate.	PR13, PR26, PR28
		The design review process shall accommodate observation or subsequent review(s) by NNSA and/or independent third parties if requested.	PR26, PR28
	Design Qualification	The design authority shall specify the qualification methods to be used to confirm customer requirements are met.	PR13, PR26, PR27
	Quamication		PR26
		Qualification test plan(s) shall be developed and documented.  Qualification test results shall also be documented.	PR26, PR27, PR28
		The design authority shall obtain concurrence from the using	PR13, PR14
		organization that specifications in design documents are complete and the detail is understood.	1 K13, 1 K14
		For the production design, the design authority shall obtain concurrence from the applicable production facilities or organization that the producibility of the design is mutually acceptable.	PR8, PR13, PR14,
3.3.4	<b>Design Documents</b>	1	PR3, PR8, PR13, PR14, PR18
3.3.4		Design information transmitted across organization interfaces shall identify the status of information provided and any incomplete items that require further evaluation, review, or approval.	PR11, PR13,
3.3.5	Design Change Control and Configuration	Changes to design inputs and final designs shall be subject to control measures (including design reviews) commensurate with the risk introduced by the change.	PR9, PR10, PR13
3.3.5	Management Management	These measures shall include evaluation of effects of the changes on the overall design and on any analyses upon which the design is based.	PR1, PR2, PR7, PR8, PR28
3.3.5		A design configuration management process shall be established and documented.	PR13, PR17, PR18, PR19
3.3.5		The process shall ensure that (a) configuration control is established as early as possible in the design process, and	PR3, PR13, PR17
3.3.5		(b) configuration control is applied to design inputs, design calculations and analyses, design qualification, and design documents.	PR3, PR13, PR17
3.3.6	Interface Control	Design interfaces shall be identified and controlled.	PR3, PR13
3.3.7	Records	Complete and accurate records of design shall be maintained and retrievable.	PR13

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
3.4	Instructions, Procedures and Drawings	Work shall be prescribed by and performed in accordance with documented instructions, procedures, drawings, specifications, other documents, or models that include or reference appropriate quantitative or qualitative acceptance criteria for determining	PR3, PR9, PR10, PR11, PR13
3.4		Current instructions, procedures, drawings, specifications, other documents, and models shall be available to and used by the personnel performing the work.	PR3, PR13, PR14
3.5	<b>Document Control</b>		PR3, PR4, PR11, PR13, PR14
3.5		A documented process shall be established and maintained to control documents, including models and data.	PR3, PR13, PR14
3.5		The process shall define responsibility for preparing, reviewing, approving, issuing, and distributing documents that are adequate, complete, and correct.	PR3, PR11, PR13, PR20
3.5		The process shall ensure a. identification of controlled documents;	PR14, PR17
3.5		b. identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents;	PR11, PR14, PR17, PR20
3.5		c. review of controlled documents for completeness, and approval prior to distribution;	PR17, PR18, PR20, PR21
3.5		d. correct documents are used;	PR17
3.5		e. documents specify effectivity; and	PR17, PR18
3.5		f. timely release, distribution, and implementation.	PR20, PR21, PR22
3.6	Procurement	The procurement process shall be documented and ensure that a. procurement documents contain correct requirements;	PR3, PR15, PR16
3.6		b. prospective suppliers are evaluated and selected on the basis of specified criteria;	PR3, PR15, PR16
3.6		c. procured items and services meet established requirements and perform as specified; and	PR3, PR15, PR16
3.6		d. Suppliers continue to provide acceptable items and services.	PR3, PR15, PR16
3.6.1	Supplier Evaluation,	The Purchaser shall select Suppliers on the basis of assessment of ability to meet requirements, including quality requirements.	PR3, PR13, PR15, PR16
3.6.1	Selection, and Monitoring	Supplier evaluation and selection shall be documented and shall include one or more of the following:  a. Supplier's history and current capability for providing an identical or similar product that performs satisfactorily in actual use;	PR15, PR16
3.6.1		b. Supplier's current quality records supported by documented information that can be objectively evaluated; or	PR15, PR16
3.6.1		c. Supplier's capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's quality management system.	PR15, PR16
3.6.1		Suppliers shall be monitored with regard to the effectiveness of their quality management system and the quality of their product.	PR3, PR15, PR16
3.6.1		NNSA and its contractors reserve the right to perform quality surveys and inspections at vendor and Supplier locations where materials or services are rendered under a contractor's purchase order or contract.	

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
Number			
3.6.2	Procurement	Procurement documents shall specify that the Supplier have an	PR15, PR16, section 4.3.2
	Documentation	effective quality management system that complies with the	Overview Description
		applicable requirements of this document.	
3.6.2		Procurement documents shall be controlled.	PR17, PR18
3.6.2		They shall identify documentation required, indicate records to	PR17, PR18
		be submitted or maintained, and specify record retention and	
2.12		disposition requirements.	
3.6.2		Procurement documents shall provide for return of	
		nonconforming material, access to the Supplier's facility, and	
3.6.3	Acceptance of	inspection of records by the procuring agency and NNSA.  Procurement of Third Party Products	
3.0.3	Procured Items,	1 Tocurement of Timu Larry Froducts	
	Materials and		
	Services		
	Items and	Items and materials shall be evaluated to determine	PR15, PR16
	Materials	conformance to applicable specifications.	1 K13, 1 K10
	Water lais		PR15, PR16
		When Supplier provided reports are used as a basis of acceptance, the reported results shall be compared with	PK13, PK10
		requirements.	
		The validity of Supplier provided reports shall be periodically	PR15, PR16, PR28
		verified by the purchaser by at least one of the following	
		methods: (a) independent evaluation to requirements, or	
		(b) assessment (to establish the validity of the Supplier-	PR15, PR16, PR28
		provided reports).	1113,1110,1120
	Services	In cases involving procurement of services only (such as third	PR26, PR27, PR28
		party inspection; engineering and consulting services;	,
		assessment; and installation, repair, overhaul, or maintenance	
		work), the Purchaser shall accept the service by any or all of	
		the following a) technical variability	
		b. surveillance and/or assessment of the activity, or	PR26, PR27, PR28
		c. review of objective evidence for conformance to the	PR28
		procurement document requirements.	
3.6.4	Certificate of Conf	<del>-</del>	N/A
3.7	Identification,	A process shall be established and documented so that items	H/W - N/A;
	Control and	are identified and controlled to ensure proper use and	S/W - PR17
	Status of Items	maintained to prevent damage, loss, or deterioration.	
3.7		Physical identification shall be used where possible.	H/W - N/A;
			S/W - PR17
3.7		Identification markings shall be applied using materials and	H/W - N/A;
		methods that provide a clear and legible identification and do	S/W - PR17
		not degrade the function or service life of the item.	
3.7		Where practical, markings shall be transferred to each part of	H/W - N/A;
		an identified item when subdivided and shall not be obliterated	S/W - PR17
		or hidden unless other means of identification are substituted.	
3.7		Where physical identification on the item is either impractical	H/W - N/A;
		or insufficient, physical separation, procedural control, or other	S/W - PR17
2.7		appropriate means shall be employed.	TT/XX/ NT/A
3.7		Markings, authorized stamps, tags, labels, routing cards, physical location, or other suitable means shall identify the	H/W - N/A;
		status of items from the initial receipt and fabrication of items	S/W - PR17
		up to and including use.	
<u> </u>			•

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
3.7		When required, traceability of an item shall ensure applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records.	H/W - N/A; S/W - PR17
3.7		The process shall provide for maintenance or replacement of markings and identification records due to damage from handling or aging, as well as protection of identifications on items subject to excessive deterioration due to environmental exposure.	H/W - N/A; S/W - PR3, PR17
3.7		The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and that items which have not passed the required	PR26, PR27, PR28
3.7.1	<b>Tooling and Fixtur</b>		N/A
3.7.2	Limited-Life Mater	rials and Components	N/A
3.7.3	Materials or Items	Designated for Destructive Testing	N/A
3.7.4	<b>Special Instruction</b>	s and Environments	N/A
3.8	Control of Processes	Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.	PR3, PR17
3.8		To the extent practical, criteria for workmanship shall be stipulated in written standards or by means of representative standards.	PR3, PR17
3.8		Processes shall be characterized, documented, and maintained under controlled conditions to minimize variability and to prevent nonconformance.	PR3, PR17
3.8		Proposed process changes shall be evaluated for their potential impact on quality, producibility, and maintainability prior to incorporation.	PR3,PR4, PR5, PR17
3.8		The design authority and production organization shall jointly qualify processes (including inspection, test, and acceptance processes) and document the qualification prior to use for production and acceptance.	PR3, PR20, PR21, PR26
3.8		Equipment used for process monitoring	N/A
3.8		A process to formally suspend weapon work	N/A
3.8		The process shall establish measurable criteria	N/A
3.8		Records shall be maintained for all situations	N/A
3.8.1	Process Control Methods	When production quantities are sufficient in number, statistical methods (such as statistical process control) shall be used to ensure continuous control over production processes and to identify and continually reduce variability.	PR3, PR4, PR5
3.8.1		When production quantities are not large enough to permit the use of statistical methods, alternative control methods shall be applied, such as 100 percent test and inspection when that degree of rigor is necessary to confirm compliance to specification.	Appendix F
3.8.2	Special Processes	Special processes shall be identified and procedures, processes, and controls implemented to ensure a high level of confidence in the control of product variability and to minimize nonconformances.	PR4, PR5

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
3.8.2		Special-process equipment and procedures shall be	N/A
		When the outcome of a special process is dependent upon the skill of the person performing the process, that person shall be certified to written procedure.	PR29, PR30
3.8.2		Evidence of qualification of equipment and procedures and certification of personnel shall be maintained.	PR30
3.8.2		When available, codes and standards (including acceptance criteria for the process) shall be specified or referenced in procedures or instructions.	PR3
3.8.2		For special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.	PR3, PR29, PR30
3.9	Inspection, Test and Acceptance	Inspection and testing of specified items, services, and processes shall be conducted under controlled conditions using established acceptance and performance criteria.	PR4, PR5 (processes), PR27 (software)
3.9		Inspection and test requirements and results shall be documented.	PR26, PR27, PR28
3.9		Equipment used for inspections and tests shall be	N/A
3.9		Measurement uncertainty requirements and capability of inspection and test processes shall be determined and documented.	PR3, PR4, PR5
3.9		Qualified persons other than those who perform or directly supervise the work being inspected or tested shall perform acceptance inspections and tests verifying product conformance to design criteria.	PR27, PR28
3.9		Where independent inspections and tests are not feasible because of special requirements, the responsible organization shall develop an alternative method, document it and the basis for requesting exception, and obtain design authority approval for use.	PR26
3.9		There shall be a documented process and procedures for contractor submittal of completed product and for NNSA acceptance of that product.	PR3, PR20, PR21, PR26
3.9		The process shall ensure that product was manufactured to and conforms to the correct design definition and that the quality evidence is correct and represents that product.	PR27, PR28
3.9		When automated manufacturing processes are used	N/A
3.9		When fixtures, molds, and other such tooling are used	N/A
3.9		These devices shall be controlled and recertified	N/A
3.9		When material requires modification, repair, or	N/A
3.9	G	Sampling plans shall prescribe random sampling	N/A
3.10		ing and Test Equipment	N/A
3.11.1	Government-Furni		N/A
3.11.2	NNSA-Accepted M		N/A
3.12	Nonconformance	Whenever a weapon program requirement of any type is not met, a nonconforming condition exists.	PR5, PR10, PR12, PR18, PR28
3.12		Nonconforming conditions include, but are not limited, to nonconforming operations, activities, procedures, software, and items (including material and product).	PR5, PR10, PR12, PR18, PR28

QC-1	QC-1	QC-1	ASC Software
Section	Section Title	Requirements	Quality Plan
Number	Occilon Title	Requirements	Quality I lail
3.12		When a natural an actual nonconforman as is identified the	DD5 DD10 DD12 DD10
3.12		When a potential or actual nonconformance is identified, the	PR5, PR10, PR12, PR18, PR28
		situation shall be evaluated and appropriate action shall be taken.	11.20
3.12		A process shall be documented to prescribe actions to address	PR3, PR10, PR12, PR18
3.12		potential and actual nonconforming conditions.	1113, 11110, 11112, 11110
3.12		Procedures shall be established and maintained that define	PR3, PR4, PR5
3.12		processes for identifying, investigating, and dispositioning	110,110
		nonconforming conditions.	
3.12		These procedures shall clearly define the level and	PR3, PR11, PR29
		qualification of personnel authorized to disposition	
		nonconformances.	
3.12		Personnel performing evaluations to determine disposition of a	PR11, PR29, PR30
		nonconformance shall have demonstrated competence in the	
		specific area they are evaluating, have an adequate	
		understanding of the requirements, and have access to pertinent	
2.12.1	N	background information.	ът/ A
3.12.1	Nonconforming Ite		N/A
3.12.2	Nonconforming Ite		N/A
3.13	Corrective Action	A process shall be established and documented for corrective	PR3, PR4, PR5, PR9, PR12
		action, and procedures shall be established and implemented to	
		a. identify and categorize conditions adverse to quality (including criteria for determining significant conditions	
		adverse to quality);	
3.13		b. track, trend, and report conditions adverse to quality;	PR10, PR12, PR18
3.13		c. apply compensatory measures;	N/A
3.13		d. perform causal analysis of a significant condition adverse to	PR5, Appendix F
5.15		quality to determine if the condition is incidental or systemic;	11.0,11.pp.01101111
3.13		e. develop and implement corrective action to preclude	PR10, PR12
3.13		recurrence;	11110,11112
3.13		f. verify that the corrective action precludes a recurrence of the	
		condition adverse to quality; and	
3.13		g. capture and communicate lessons learned internally and to	PR5
0.10		NNSA for use in preventing problems and making	
		improvements.	
3.13		Recurring deficiencies are an indication of systemic failure of	PR1, PR3, PR4, PR5
		the quality management system.	
3.13		Senior management shall take appropriate action to determine	
		the cause(s) and permanently correct the systemic problem.	
3.14	Records	A process shall be established and documented for records	PR3
		management.	
3.14		Records shall be specified, prepared, reviewed, approved, and	section 4.2.3
		maintained to demonstrate achievement of quality	
		requirements and effective operation of the quality	
		management system.	
3.14		Procedures shall be established and implemented for the	
		identification, collection, organization, filing, storage,	
		maintenance, retrieval, distribution, retention, and disposition of records.	
3.14		Records shall be maintained to furnish objective evidence that	PR17, section 4.1
3.14		items or activities meet specified requirements.	"Artifacts"
		none of activities meet specifica requirements.	1 H HIGGS

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
3.14		Records shall be identifiable as a record; completely and accurately reflect the work accomplished or information required; be legible; and be traceable to associated requirements, items, and activities.	PR17, section 4.1 "Artifacts"
3.14		Records may be originals, copies, or electronic.	PR17, section 4.1 "Artifacts"
3.14		Records shall be authenticated and dated by authorized personnel.	PR17, section 4.1 "Artifacts"
3.14		Acceptable methods of authentication include statements of authenticity, handwritten signatures, electronic signatures, or any other means that ensure traceability to a specific authenticating individual and organization and to an authentication date.	
3.14		Records shall be stored such that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss.	PR17, PR19
3.14		Records management shall comply with DOE O 200.1, Information Management Program.	
3.15	Assessments	Management and independent assessments shall be planned and conducted to (a) evaluate item and service quality,	section 5, Table 1, PR25, PR27
3.15		(b) measure the adequacy of work performance, and	Table 1, PR12
3.15		(c) promote improvement.	section 5, Table 1
3.15		Processes for management assessments and independent assessments shall be established and documented.	Table 1, PR3, section 5
3.15		Managers shall assess their management processes.	Table 1, PR2, section 5
3.15		Problems that hinder the organization from achieving its objectives shall be identified and corrected.	Table 1, PR2, section 5
3.15		Personnel performing independent assessments shall have sufficient authority and freedom from the line organization to carry out their responsibilities.	section 5
3.15.1	Assessor Qualification	Personnel conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.	section 5, PR28
3.15.1		Personnel conducting independent assessments shall be qualified to a documented set of criteria, including education, training, and experience.	section 5, PR28
3.15.2	Scheduling	Risk (considering the status, history, and importance of the activity) shall be used as a basis for scheduling management and independent assessments.	Table 1, section 5
3.15.2		The management and independent assessment schedules and associated risk bases shall be documented.	section 5, PR11
3.15.3	Planning	Management and independent assessment plans shall be established and documented.	section 5, PR11, Table 1
3.15.3		The plans shall identify the objectives, scope, approach, and performance criteria to be used.	section 5, PR12
3.15.4	Performance	Management and independent assessments shall compare actual performance with performance criteria.	section 5, PR12
3.15.4		Objective evidence shall be examined to the depth necessary to determine if requirements and criteria are being met.	section 5, PR11, PR12
3.15.4		Conditions requiring prompt corrective action shall be reported immediately to management of the assessed organization.	section 5, PR11, PR12

QC-1	QC-1	QC-1	ASC Software
Section Number	Section Title	Requirements	Quality Plan
3.15.5	Reporting	Management and independent assessment reports shall be prepared, signed and dated by the lead assessor, and sent to the responsible management in accordance with established procedures.	section 5, PR11, PR12
	Management Assessment Reporting	Management assessment reports shall include a. an identification and summary of underlying assessments performed,	PR3, PR11, section 5
		<ul><li>b. a discussion of deficiencies identified and trends,</li><li>c. an evaluation of the effectiveness of corrective actions, and</li><li>d. a discussion of continuous improvement initiatives.</li></ul>	PR3, PR11, section 5 PR3, PR11, section 5 PR3, PR11, section 5
	Independent Assessment Reporting	Independent assessment reports shall a. describe the assessment objectives, scope, approach, and performance requirements and quantitative criteria; b. identify assessors and persons contacted;	
		c. identify documents, material, operations, activities, and conditions assessed;	
		d. present deficiencies observed, and	
		e. summarize the extent of compliance and performance relative to assessment scope, performance requirements, and associated criteria.	
3.16	Software Quality Assurance	A software quality assurance (SQA) process shall be established to provide assurance that software will satisfy customer requirements.	Software Quality Plan
3.16		The process shall apply to software that is purchased, developed under contract, or developed by NNSA or its contractors.	Software Quality Plan
3.16		The SQA process shall address applicable elements of QC-1.	Software Quality Plan
3.16		SQA activities shall be commensurate with the complexity and the risk associated with failure of the software to meet established requirements.	PR2
3.16		A documented risk-based and graded approach shall be used to balance cost, risk and program flexibility.	PR2, Table 1
3.16		The SQA process shall use a software life-cycle management methodology based upon a consensus SQA standard or an equivalently rigorous contractor-specific standard that addresses software development from beginning to end and the flow of activities and it	PR3
3.16		Software life-cycle stages may include a. concept,	PR3
3.16		b. requirements,	PR3
3.16		c. design,	PR3
3.16		d. implementation,	PR3
3.16		e. operation,	PR3
3.16		f. maintenance, and	PR3
3.16		g. retirement.	PR3
3.16		Requirements shall be identified, testable, and controlled.	PR6, PR7, PR8
3.16		Software configuration management shall ensure a. a software baseline is established no later than the completion of the software validation process, and	PR17

QC-1 Section	QC-1 Section Title	QC-1 Requirements	ASC Software Quality Plan
Number			
3.16		b. changes subsequent to the baseline are traceable to software requirements, approved, documented, and added to the baseline so that the baseline defines the most recently approved software configuration.	PR17, PR18
3.16		Software verification and validation activities shall be controlled, documented, and demonstrate requirements are met.	PR26, PR27, PR28, section 4.4 Overview Description
4.0	Responsibilities		
4.1	Senior	Senior NNSA and Contractor management shall	CPR 1.3.2, CPR 1.3.6,
	Management	a. establish the organization's quality policy;	Software Quality Plan
4.1		b. assign responsibility for establishment, implementation, and oversight of the quality management system, including preparation of the QAP or WQAP and any associated implementation plan;	CPR 1.3.2, CPR 1.3.6, Software Quality Plan
4.1		c. actively participate in quality management system development, implementation and improvement;	CPR 1.3.2, CPR 1.3.6, Software Quality Plan
4.1		d. ensure that customer requirements are determined, documented, and met with the aim of enhancing customer satisfaction;	CPR 1.3.2, CPR 1.3.6, Software Quality Plan
4.1		e. review the organization's quality management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness; and	CPR 1.3.2, CPR 1.3.6, Table 1
4.1		f. take appropriate action to determine the cause(s) of recurring nonconformances and permanently correct the systemic problem.	CPR 1.3.2, CPR 1.3.6, Table 1

## 4 GP&G Mappings

The following chart maps between the SNL site-specific practices described in *Part 1: Practices* of the Software Quality Plan and the *ASCI Software Quality Engineering: Goals, Principles and Guidelines* (GPP&G), a report developed collaboratively as high-level SQE guidelines for software developed in the Tri-Laboratory ASCI Program.

GP8	&G SQE Guidelines	SNL Practices	
Software Verification	Technical reviews	PR26, PR28 PR26, PR28	
	Unit testing  • Traceable, repeatable component tests	PR26, PR27, PR17, PR18	
	Regression testing	PR17, PR18, PR19, PR20, PR21 PR27 PR26	
	Comparison techniques	PR26, PR27 PR26, PR27	
	<ul> <li>User acceptance testing</li> <li>Applicability evaluation</li> <li>Usability evaluation</li> <li>Code confidence</li> <li>Results credibility</li> </ul> Training	PR7, PR8, PR13, PR14, PR20, PR26, PR27, App. E, Table 2, PR28, App. E PR20, PR27, App. E Goals of SQ Plan, PR20, PR27, App. E, App. F Goals of SQ Plan, PR20, PR27, App. E, App. F	
	<ul> <li>Verification methods and techniques</li> </ul>	PR29, PR30, Table 1	
Software Engineering	<ul> <li>Lifecycle management</li> <li>Time-based work flow</li> <li>Requirements         Design         Construction         Test         Support activities     </li> </ul>	PR3 PR6, PR7, PR8 PR13 PR14 PR23, PR24 PR8, PR15, PR16, PR17, PR18, PR19, PR22, PR23, PR24, PR25	
	Configuration management  Version management Issue tracking Release management	PR15, PR16, PR17 PR18 PR17, PR18, PR19	
	Measurements and metrics	PR4, all practices suggest metrics PR4, all practices suggest metrics	
	Reviews and assessments  Management reviews  Technical reviews	PR12, section 5, App. D PR27, section 5, App. D	

GP&G SQE Guidelines		SNL Practices
	• Engineering process baseline	PR3
	Identified improvements	PR5
	Improvement implementation	PR5, PR18, PR21
	Training	PR29, PR30, Table 1
Project	Risk management	
Management	<ul> <li>Risk assessment</li> </ul>	PR9
J	Risk control	PR10
	• Gathering, documenting, verifying, managing change to requirements	PR6, PR7, PR8, PR26, PR27, PR28, PR18
	Project planning	
	<ul> <li>Statement of work</li> <li>Constraints and goals</li> <li>Implementation plan</li> <li>Resource assessment</li> </ul>	PR11 PR11 PR11 PR11
	Tracking and oversight	PR12 PR12
	Process management  • Process documentation and plans	Table 1, PR3
	<ul> <li>Technology         <ul> <li>improvement</li> </ul> </li> <li>Improvement leverage</li> </ul>	PR4, section 5, Table 1
	Training Training	PR4, section 5, Table 1
	Project management methods and techniques	PR29, PR30, Table 1

## **5 SNL Corporate Process Requirements Mappings**

This section presents the mappings for the two SNL Corporate Process Requirement (CPR) documents, CPR001.3.2 *Corporate Quality Assurance Program* and CPR001.3.6 *Corporate Software Quality Assurance*.

### 5.1 SNL CPR001.3.2 Mapping

Section 1.1, Figure 1, section 2, Table 1, PR1	CPR001.3.2 Requirements	ASC Software Quality Plan
Section 1.1, Figure 1, section 2, Table 1, PR1	1.0 Purpose	No mapping is required
Roles and Responsibilities	2.0 Statement of Applicability	Section 1.1, Figure 1, section 2, Table 1, PR1
ASC Software Quality Plan  ASC Software Quality Plan  Figure 1, section 2, Table 1, PR1, PR2  Gap – No specific tracking or trending requirement for quality.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  ASC Software Quality Issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5  ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Table 1, PR1, PR2, PR6  Base ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Base ASC Soft	3.0 Roles and Responsibilities	Roles and responsibilities for CPR001.3.2
3.3 Vice Presidents 3.4 Directors  Figure 1, section 2, Table 1, PR1, PR2 Gap – No specific tracking or trending requirement for quality.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  ASC Software Quality Plan  ASC Software Quality Plan  Done by Program and Center management – outside scope of ASC Software Quality Plan  Done by Program and Center management – outside scope of ASC Software Quality Plan  Table 1, PR1, PR2, PR6 Gap – No specific designation of using FLDS to document formality level.  Table 1, PR1, PR2, PR6, PR7, PR8 Gap – No specific designation of using FLDS to document formality level.  Gap – PAAA not addressed. Partial Gap – FLDS and formality level not referenced directly.  Table 1, PR1, PR2, PR6, Table 3	3.1 The Executive VP	
Figure 1, section 2, Table 1, PR1, PR2 Gap – No specific tracking or trending requirement for quality.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific designation of the ASC Software Quality Plan  Table 1, PR1, PR2, PR6 Gap – No specific designation of using FLDS to document formality level.  Table 1, PR1, PR2, PR6, PR7, PR8 Gap – No specific designation of using FLDS to document formality level.  Gap – PAAA not addressed. Partial Gap – FLDS and formality level not referenced directly.  Table 1, PR1, PR2, PR6, Table 3  Table 1, PR1, PR2, PR6, Table 3  Table 1, PR1, PR2, PR6, Table 3  Table 1, PR1, PR2, PR6 Partial GAP – FLDS and formality level not		ASC Software Quality Plan
Gap – No specific tracking or trending requirement for quality.  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices.  3.6 Program and Project Leaders  3.7 Members of the Workforce  3.8 Quality Assurance Working Group Representatives 3.9 Quality Assurance Working Group QWAG) 3.10 Quality Program Office (QPO) Manager 3.11 Price-Anderson Amendments Act (PAAA) Program Integration Department Manager 3.12 Audit Center and Surety Assessment Center 3.13 Directors Quality Council (DQC) 3.14 Directors Council on Software Quality 3.15 NWSMU Quality Managers Council 4.0 Implementation Requirements  Done by Program and Center management – outside scope of ASC Software Quality Plan  Table 1, PR1, PR2, PR6 Gap – No specific designation of using FLDS to document formality level.  Table 1, PR1, PR2, PR6, PR7, PR8 Gap – No specific designation of using FLDS to document formality level.  Table 1, PR1, PR2, PR6, Table 3  Table 1, PR1, PR2, PR6, Table 3  Table 1, PR1, PR2, PR6, Table 3  Table 1, PR1, PR2, PR6 Partial GAP – FLDS and formality level not		
3.5 Managers and Team Supervisors  Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap – No specific tracking or trending requirement for quality issues in the practices. Table 1, PR1, PR2, PR3, PR4, PR5 Table 1, PR1, PR2, PR3, PR4, PR5 ASC Software Quality issues in the practices. ASC Software Quality Plan ASC Software Quality Plan Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan ASC Softwar	3.4 Directors	
Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap - No specific tracking or trending requirement for quality issues in the practices. Table 1, PR1, PR2, PR3, PR4, PR5, Appendix F Gap - No specific tracking or trending requirement for quality issues in the practices. Table 1, PR1, PR2, PR3, PR4, PR5  ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 - 3.15 are outside the scope of the ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 - 3.15 are outside the scope of the ASC Software Quality Plan  ASC Software Quality Plan		
Gap – No specific tracking or trending requirement for quality issues in the practices.  Table 1, PR1, PR2, PR3, PR4, PR5  ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Borectors Quality Council (DQC)  Roles and responsibilities for CPR001.3.2 sections 3.8 – 3.15 are outside the scope of the ASC Software Quality Plan  Bone by Program and Center management – outside scope of ASC Software Quality Plan  Table 1, PR1, PR2, PR6  Gap – No specific designation of using FLDS to document formality level.  Table 1, PR1, PR2, PR6, PR7, PR8  Gap – No specific designation of using FLDS to document formality level.  Gap – PAAA not addressed.  Partial Gap – FLDS and formality level not referenced directly.  Table 1, PR1, PR2, PR6  Partial GAP – FLDS and formality level not referenced directly.	3.5 Managers and Team Supervisors	
Requirement for quality issues in the practices.	3.5 Managers and Team Supervisors	
Table 1, PR1, PR2, PR3, PR4, PR5  3.7 Members of the Workforce  3.8 Quality Assurance Working Group Representatives 3.9 Quality Assurance Working Group (QWAG) 3.10 Quality Program Office (QPO) Manager 3.11 Price-Anderson Amendments Act (PAAA) Program Integration Department Manager 3.12 Audit Center and Surety Assessment Center 3.13 Directors Quality Council (DQC) 3.14 Directors Quality Managers Council 3.15 NWSMU Quality Managers Council 3.16 Implementation Requirements  Done by Program and Center management — outside scope of ASC Software Quality Plan  1.10 Define Scope of Work  Table 1, PR1, PR2, PR6 Gap — No specific designation of using FLDS to document formality level.  3.17 Gap — PAAA not addressed.  Partial Gap — FLDS and formality level not referenced directly.  3.18 PR1, PR2, PR6 Partial GAP — FLDS and formality level not Table 1, PR1, PR2, PR6 Partial GAP — FLDS and formality level not		
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3.9 Quality Assurance Working Group (QWAG) 3.10 Quality Program Office (QPO) Manager 3.11 Price-Anderson Amendments Act (PAAA) Program Integration Department Manager 3.12 Audit Center and Surety Assessment Center 3.13 Directors Quality Council (DQC) 3.14 Directors Council on Software Quality 3.15 NWSMU Quality Managers Council 4.0 Implementation Requirements  Done by Program and Center management — outside scope of ASC Software Quality Plan 4.1 Define Scope of Work  Table 1, PR1, PR2, PR6 Gap — No specific designation of using FLDS to document formality level. 4.2 Define Formality levels  Table 1, PR1, PR2, PR6, PR7, PR8 Gap — No specific designation of using FLDS to document formality level. Gap — PAAA not addressed. Partial Gap — FLDS and formality level not referenced directly.  4.2.1 Formality Level Criteria  Table 1, PR1, PR2, PR6, Table 3  Table 1, PR1, PR2, PR6 Partial GAP — FLDS and formality level not	3.7 Members of the Workforce	ASC Software Quality Plan
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high 1.2.3 Determine PAAA applicability Gap – PAAA not addressed.	4.2.3 Determine PAAA applicability	O Company of the comp
7.2.5 Determine I AAA applicability Gap - FAAA not addressed.	7.2.5 Determine I AAA applicationty	Gap - I AAA not audi esseu.

CPR001.3.2 Requirements	ASC Software Quality Plan
4.3 Establish Controls	Section 2, Table 1, PR1, PR2, PR6, PR3  Gap - no specific reference to individuals being able to demonstrate this requirement.
4.3.1 Application of the Graded Approach	Table 1, PR1, PR2, PR6
4.4 Feedback and Improvement	Table 1, PR1, PR3, PR4, PR5, PR12, Section 5, PR28
4.4.1 Trigger Issue Criteria	Gap – reporting quality issues to the QAWG Gap – no specific reference to escalation of significant quality issues.
5.0 Quality Assurance Criteria	
The Quality Assurance requirements are taken from DOE O 414.1. A "Quality Assurance Requirements." The ten criteria are applied accordance with the level of formality using the graded approach. To Management, Performance, and Assessment.	to all scope of work and implemented in
Management	
Criteria 1 – Program	
• A written QAP must be developed, implemented, and maintained.	ASC Software Quality Plan
• The QAP must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.	Table 1, PR1-PR30, Section 5
<ul> <li>The QAP must describe management processes, which includes planning, scheduling, and resource considerations.</li> </ul>	Table 1, PR1, PR2, PR3, PR11, PR12
<ul> <li>Criteria 2 - Personnel Training and Qualification</li> <li>Personnel must be trained and qualified to ensure that they are capable of performing their assigned work.</li> </ul>	Table 1, PR11, PR29, PR30
• Personnel must be provided continuing training to ensure that job proficiency is maintained.	Table 1, PR29, PR30
<ul> <li>Criteria 3 – quality improvement</li> <li>Process to detect and prevent quality problems must be established and implemented</li> </ul>	PR3, PR4, PR5, PR9, PR10, PR12, PR13, PR18, PR27, PR28
• Items, services and processes that do not meet established requirements must be identified, controlled, and corrected according to the importance of the problems and the work affected. Correction must include identifying the causes of the	PR4, PR5, PR8, PR9, PR10, PR12, PR17, PR18, PR19, PR27, PR28, Appendix E
<ul> <li>problems and working to prevent reoccurrence.</li> <li>Items characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.</li> </ul>	PR3, PR4, PR5, PR10, PR12, PR13, PR17, PR18, PR27, PR28
<ul> <li>Criteria 4 – documents and records</li> <li>Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.</li> </ul>	PR3, PR4, PR5, PR7, PR8, PR13
Records must be specified, prepared, reviewed, approved, and maintained	PR1-PR30
Performance	
<ul> <li>Criteria 5 – Work Processes</li> <li>Work must be preformed to establish technical standards and administrative controls, using approved instructions, procedures or other appropriate means</li> </ul>	Table 1, PR1, PR2, PR3, PR11
• Items must be identified and controlled to ensure their proper use	PR17
• Items must be maintained to prevent their damage, loss, of deterioration	PR 7, PR8, PR9, PR13, PR14, PR17, PR19

CPR001.3.2 Requirements	ASC Software Quality Plan
Equipment used for process monitoring or data collection must be calibrated and maintained.	N/A
Criteria 6 – Design  Items and processes must be designed using sound  an air again a (reinstiff a principles and appropriate standards).	PR3, PR13, PR28
<ul> <li>engineering/scientific principles and appropriate standards</li> <li>Design work, including changes, must incorporate applicable requirements and design bases</li> </ul>	PR7, PR8, PR11, PR12, PR13, PR28
Design interfaces must be identified and controlled	PR13, PR17
The adequacy of design products must be verified or validated by individuals or groups other than those who perform the work	PR13, PR26, PR27, PR28, Section 4.4, Overview Description
Verification and validation work must be completed before approval and implementation of the design	PR26, PR27, PR28 PR27, PR28 address performing test and evaluation of work products, including design. Not all V&V activities will be completed prior to approval of design.
<ul> <li>Criteria 7 – Procurement</li> <li>Procured items and services must meet established</li> </ul>	Outside the scope of the ASC Software Quality
<ul> <li>requirements and perform as specified</li> <li>Prospective suppliers must be evaluated and selected on the</li> </ul>	Plan
basis of specified criteria	
<ul> <li>Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.</li> </ul>	
<ul> <li>Criterion 8 – Inspection and Acceptance Testing</li> <li>Inspection and testing of specified items, services, and processes must be conducted using established acceptance and performance criteria</li> </ul>	Table 1, PR5, PR14, PR26, PR27, PR28
Equipment used for inspections and tests must be calibrated and maintained	N/A
Assessment	
<ul> <li>Criterion 9 – Management Assessment</li> <li>Managers must assess their management processes</li> </ul>	Table 1, PR1, PR2, PR3, PR4, PR5
Problems that hinder the organization from achieving its objectives must be identified and corrected	Table 1, PR1, PR2, PR3, PR4, PR5, PR8, PR10, PR12
Criterion 10 – Independent Assessment     Independent assessments must be planned and conducted to measure item and service quality, to measure adequacy of	Table 1, PR12, PR27, PR28, Section 5
<ul> <li>work performance, and to promote improvement.</li> <li>The group performing independent assessment must have sufficient authority and freedom from the line organization to carry out its responsibilities</li> </ul>	Table 1, Section 5
Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed	Table 1, Section 5
6.0 Required Records	Table 1, PR1, PR17, Table 6 "Software Quality Plan Artifacts"  Gap –FLDS approval
7.0 References	Section 1, Figure 1, Section 2 addresses GP&G, CPR1.3.2, CPR1.3.6. 414A
7.1 Drivers 7.2 DOE Guidance 7.3 Sandia Guidance	is now part of QC-1 which is covered by the CPR's. QC-1 via CPR's, 414 in QC-1 via CPR's

## **5.2 CPR001.3.6 Mappings**

CPR001.3.6	ASC Software Quality Plan
Requirements	
1.0 Purpose	Part 1: section 1, section 1.1, PR6, PR7, PR8, PR11, PR12, PR21, PR25, PR27, PR28 Establishing confidence in codes is one of the goals of the GP&G. The GP&G's key elements are associated with activities that, in turn, are related to the guideline areas. The guideline areas support the principles that, in turn, support the goals. A mapping has been done between the GP&G activities and key elements and the ASC Software Quality Plan. The GP&G mappings are in both Part 1 (Appendix G) and Part 2 (section 4).
2.0 Statement of Applicability	Part 1: section 1, section 1.1, Figure 1, section 2
3.0 Policy Requirements	Part 1: Table 1, PR1, PR2, PR3, PR4, PR5, PR6 This appears to be a gap in the quality plan. There is no specific reference to reporting and a corporate level in the plan.
1. Project Planning and Oversight	Part 1: PR11, PR12
2. Requirements Management	Part 1: PR1, PR6, PR7, PR8, PR23
3. Configuration Management	Part 1: PR17, PR18
4. Process and Work Product Verification	Part 1: PR27, PR28, Section 5
5. Software Product Engineering	Part 1: PR3, PR7, PR8, PR13, PR14, PR26, PR27, PR28
6. Training	Part 1: PR11, PR29
7. Peer Review of Software Inspection	Part 1: PR26, PR27, PR28
8. Inter-group Coordination	Part 1: Table 1, PR1
4.0 Definitions	No mapping required
5.0 Drivers	No mapping required
6.0 Resources and References	No mapping required
7.0 Attachment: Templates and Examples	No mapping required

## **6** ISO 9001-2000 Mapping

The following chart maps requirements between *Part 1: Practices* of the Software Quality Plan and the ISO 9001-2000 document.

ISO 9001:2000 Quality Management Systems – Requirements	ASC Software Quality Plan
1 Scope	
1.1 General	
This International Standard specifies requirements for a quality management	
system where an organization	
a) needs to demonstrate its ability to consistently provide product that meets	Section 1.1, PR3-5, PR6-8,
customer and applicable regulatory requirements, and b) aims to enhance	PR25
customer satisfaction through the effective application of the system, including	
processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.	
1.2 Application	
All requirements of this International Standard are generic and are intended to	
be applicable to all organizations, regardless of type, size and product provided.	
Where any requirement(s) of this International Standard cannot be applied due	
to the nature of an organization and its product, this can be considered for	
exclusion.	ISO 9001:2000 §7.6, Control of
Where exclusions are made, claims of conformity to this International Standard	monitoring and measuring
are not acceptable unless these exclusions are limited to requirements within	devices, is an allowed exclusion
clause 7, and such exclusions do not affect the organization's ability, or	
responsibility, to provide product that meets customer and applicable regulatory	
requirements.	
2 Normative reference	N/A
3 Terms and definitions	Some ISO 9000:2000
For the purposes of this International Standard, the terms and definitions given	definitions are referenced in the
in ISO 9000 apply. The following terms, used in this edition of ISO 9001 to	Glossary (e.g. "requirement").
describe the supply chain, have been changed to reflect the vocabulary	The set of definitions (which
currently used: supplier -> organization -> customer	words included) is different.
Throughout the text of this International Standard, wherever the term "product"	Also, definitions are different
occurs, it can also mean "service".	from QC-1.
4 Quality management system	
4.1 General requirements	AGG G G G L'A PI
The organization shall establish, document, implement and maintain a quality	ASC Software Quality Plan
management system and continually improve its effectiveness in accordance with the requirements of this International Standard.	
The organization shall	
a) identify the processes needed for the quality management system and their	
application throughout the organization (see 1.2),	PR1, PR3
b) determine the sequence and interaction of these processes,	PR3
c) determine criteria and methods needed to ensure that both the operation and	PR3, PR4, PR5
control of these processes are effective,	116,116,116
d) ensure the availability of resources and information necessary to support the	PR4, PR5, PR11
operation and monitoring of these processes,	
e) monitor, measure and analyze these processes, and	PR3, PR4, PR5
f) implement actions necessary to achieve planned results and continual	PR5
improvement of these processes.	
These processes shall be managed by the organization in accordance with the	
requirements of this International Standard.	
Where an organization chooses to outsource any process that affects product	

ISO 9001:2000	ASC Software Quality
Quality Management Systems – Requirements	Plan
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conformity with requirements, the organization shall ensure control over such	
processes. Control of such outsourced processes shall be identified within the	
quality management system.	
4.2 Documentation requirements	
4.2.1 General  The quality management system decumentation shall include	
The quality management system documentation shall include a) documented statements of a quality policy and quality objectives,	Section 1, Section 2, Section 3
b) a quality manual,	ASC Software Quality Plan
c) documented procedures required by this International Standard,	ASC Software Quality Plan
d) documents needed by the organization to ensure the effective planning,	PR3, PR4, PR5
operation and control of its processes, and	
e) records required by this International Standard (see 4.2.4).	PR17, PR19
4.2.2 Quality manual	
The organization shall establish and maintain a quality manual that includes	
a) the scope of the quality management system, including details of and	Sections 1-3, PR1, PR2
justification for any exclusions (see 1.2),	
b) the documented procedures established for the quality management system,	PR3
or reference to them, and	DD2
c) a description of the interaction between the processes of the quality	PR3
management system.  4.2.3 Control of documents	
Documents required by the quality management system shall be controlled.	
Records are a special type of document and shall be controlled according to the	
requirements given in 4.2.4.	
A documented procedure shall be established to define the controls needed	
a) to approve documents for adequacy prior to issue,	PR3
b) to review and update as necessary and re-approve documents,	PR3
c) to ensure that changes and the current revision status of documents are	PR17
identified,	
d) to ensure that relevant versions of applicable documents are available at	PR17, PR22
points of use,	DD 17
e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin are identified and their	PR17 PR15, PR16, PR17, PR22
distribution controlled, and	FK13, FK10, FK17, FK22
g) to prevent the unintended use of obsolete documents, and to apply suitable	PR17, PR22
identification to them if they are retained for any purpose.	11117, 11122
4.2.4 Control of records	
Records shall be established and maintained to provide evidence of conformity	PR3, PR17, PR18, PR19,
to requirements and of the effective operation of the quality management	Section 4.3.3 Configuration
system. Records shall remain legible, readily identifiable and retrievable. A	Management, Overview
documented procedure shall be established to define the controls needed for the	Description
identification, storage, protection, retrieval, retention time and disposition of	CPR 400.2.13 defines SNL
records.	records policy
5 Management responsibility	
<b>5.1 Management commitment</b> Top management shall provide evidence of its commitment to the development	
and implementation of the quality management system and continually	Commitment, Table 1
improving its effectiveness by	Communicity, 1 abic 1
a) communicating to the organization the importance of meeting customer as	Sections 1-3, Table 1, PR1
well as statutory and regulatory requirements,	
b) establishing the quality policy,	Sections 1-3, Table 1
c) ensuring that quality objectives are established,	Sections 1-3, Table 1
d) conducting management reviews, and	Table 1, PR1, PR12
e) ensuring the availability of resources.	Table 1, PR1, PR11

ISO 9001:2000 Quality Management Systems – Requirements	ASC Software Quality Plan
<b>5.2 Customer focus</b> Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).	Commitment, Table 1, PR1, PR6, PR7, PR8, PR23, PR24, PR25
5.3 Quality policy Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,	Table 1, PR1 Section 1.1, Figure 1, Section 2, Table 1, PR1
c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	Table 1, PR1 Table 1, PR1 Table 1, PR1
5.4.1 Quality objectives  Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable	Section 1.1, Table 1, PR1
and consistent with the quality policy.  5.4.2 Quality management system planning  Top management shall ensure that a) the planning of the quality management system is carried out in order to	Table 1, PR1
meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	Table 1, PR1
5.5 Responsibility, authority and communication	
<b>5.5.1 Responsibility and authority</b> Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.	Table 1, PR1-3, PR6 , PR11
Top management representative Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of customer requirements throughout the organization.  NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	Table 1, PR1-5, PR7-8, PR11-12, section 5 PR3-5, PR7-8, PR11-12, section 5 PR1, PR3-5, PR7-8, PR11-12,
<b>5.5.3 Internal communication</b> Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	Table 1, PR1, PR11
5.6 Management review	
<b>5.6.1 General</b> Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).	Table 1, PR1, section 5
5.6.2 Review input  The input to management review shall include information on a) results of audits,	(audits & audit reports) Table 1, PR1, PR28, section 5 PR6-8, PR25

ISO 9001:2000 Quality Management Systems – Requirements	ASC Software Quality Plan
b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement.	PR9-10, PR11-12, PR13-16, PR17-19, PR27, PR28 PR4, PR10, PR12, PR17 PR11-12 PR5, section 5 Table 1, PR1, PR5, PR12, PR25, PR28, section 5
<b>5.6.3 Review output</b> The output from the management review shall include any decisions and actions related to	Table 1, PR1
a) improvement of the effectiveness of the quality management system and its processes,	PR11-12
b) improvement of product related to customer requirements, and c) resource needs.  6 Resource management	PR11-12 PR1, PR11-12
6.1 Provision of resources	
The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and	Table 1, PR1-5
b) to enhance customer satisfaction by meeting customer requirements.	PR1-PR3, PR6-8, PR11, PR25
6.2 Human resources	
<b>6.2.1 General</b> Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	Table 1, PR1, PR11-12, PR29-30
6.2.2 Competence, awareness and training The organization shall	
a) determine the necessary competence for personnel performing work affecting product quality,	PR29
b) provide training or take other actions to satisfy these needs,	PR30
c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,	PR12, PR28 PR11, PR29
and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	PR30
6.3 Infrastructure	
The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable	
a) buildings, workspace and associated utilities,	PR1, PR11
b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).	PR13, PR15-16 PR1, PR11-12
6.4 Work environment	
The organization shall determine and manage the work environment needed to	PR1, PR11
achieve conformity to product requirements.  7 Product realization	
The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization shall determine the	
following, as appropriate: <ul><li>a) quality objectives and requirements for the product;</li><li>b) the need to establish processes, documents, and provide resources specific to</li></ul>	PR1-3, PR6-8, PR20 PR1-3, PR11, PR20

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the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).	PR8, PR11-12, PR17-19, PR21, PR26-28 PR17-19, PR21, PR26-28
7.2 Customer-related processes	· · · · · · · · · · · · · · · · · · ·
7.2.1 Determination of requirements related to the product	
The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,	PR6-8, PR23
b) requirements not stated by the customer but necessary for specified or intended use, where known,	PR6-8, PR23
c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	PR8, PR13, PR15-16 PR8, PR9-10
7.2.2 Review of requirements related to the product  The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or	Table 1, PR1, PR28
orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and	PR6-8 PR8, PR11-12
c) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	PR9-10, PR11-12
Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	
7.2.3 Customer communication The organization shall determine and implement effective arrangements for	
communicating with customers in relation to a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.	PR6-8, PR13, PR23-PR25 PR6-8, PR13, PR23-PR25 PR6-8, PR23-PR25
7.3 Design and development	
<ul> <li>7.3.1 Design and development planning</li> <li>The organization shall plan and control the design and development of product.</li> <li>During the design and development planning, the organization shall determine</li> <li>a) the design and development stages,</li> <li>b) the review, verification and validation that are appropriate to each design and development stage, and</li> </ul>	PR1- 3, PR11, PR13 PR11, PR13, PR26
c) the responsibilities and authorities for design and development.  The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.	PR1, PR6, PR11, PR13
7.3.2 Design and development inputs Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development.	PR1, PR3, PR6-8, PR13 PR6-8, PR13, PR15-16 PR6-8, PR13, PR15-16

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These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	PR9-10, PR28	
<b>7.3.3 Design and development outputs</b> The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.		
Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision,	PR13, PR15-16, PR28 PR13, PR15-16, PR28	
c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.	PR27-28 PR23	
7.3.4 Design and development review At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and	Table 1, PR1, PR3, PR11, PR13, PR17-19, PR28	
b) to identify any problems and propose necessary actions.  Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	PR5, PR8, PR12, PR17-19	
7.3.5 Design and development verification  Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).	PR17-19, PR26-28	
7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	PR17-19, PR26-28	
7.3.7 Control of design and development changes Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained. 7.4 Purchasing	PR8, PR13, PR17-19, PR23-25, PR26-28, PR15-16	
7.4.1 Purchasing process  The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.  The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	PR15-16, PR17-19	

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7.4.2 Purchasing information	
Purchasing information shall describe the product to be purchased, including	
where appropriate	
a) requirements for approval of product, procedures, processes and equipment,	PR6-8, PR11, PR29-30
b) requirements for qualification of personnel, and	
c) quality management system requirements.	PR11, PR29-30
The organization shall ensure the adequacy of specified purchase requirements	PR6-8, PR11, PR29-30
prior to their communication to the supplier.	
7.4.3 Verification of purchased product	
The organization shall establish and implement the inspection or other activities	PR15-16, PR26-28
necessary for ensuring that purchased product meets specified purchase	
requirements. Where the organization or its customer intends to perform	
verification at the supplier's premises, the organization shall state the intended	
verification arrangements and method of product release in the purchasing	
information.	
7.5 Production and service provision	
7.5.1 Control of production and service provision	
The organization shall plan and carry out production and service provision	
under controlled conditions. Controlled conditions shall include, as applicable	
a) the availability of information that describes the characteristics of the	PR23-25
product,	
b) the availability of work instructions, as necessary,	PR23-25, PR29-30
c) the use of suitable equipment,	PR11-12
d) the availability and use of monitoring and measuring devices,	PR11-12
e) the implementation of monitoring and measurement, and	PR3-5
f) the implementation of release, delivery and post-delivery activities.	PR20-22, PR23-25
7.5.2 Validation of processes for production and service provision	
The organization shall validate any processes for production and service	
provision where the resulting output cannot be verified by subsequent	
monitoring or measurement. This includes any processes where deficiencies	
become apparent only after the product is in use or the service has been	
delivered.	
Validation shall demonstrate the ability of these processes to achieve planned	
results.	
The organization shall establish arrangements for these processes including, as	
applicable	DD26 29
a) defined criteria for review and approval of the processes,	PR26-28 N/A
<ul><li>b) approval of equipment and qualification of personnel,</li><li>c) use of specific methods and procedures,</li></ul>	PR3
d) requirements for records (see 4.2.4), and	CRP400.2.13 defines SNL
a) requirements for records (see 4.2.4), and	policy
e) revalidation.	PR8
7.5.3 Identification and traceability	110
Where appropriate, the organization shall identify the product by suitable	PR1, PR7-8, PR26-28, PR15-
means throughout product realization. The organization shall identify the	16, PR17-19
product status with respect to monitoring and measurement requirements.	10,11(1)
Where traceability is a requirement, the organization shall control and record	
the unique identification of the product (see 4.2.4).	
7.5.4 Customer property	
The organization shall exercise care with customer property while it is under	PR15-16
the organization's control or being used by the organization. The organization	
shall identify, verify, protect and safeguard customer property provided for use	
or incorporation into the product. If any customer property is lost, damaged or	
otherwise found to be unsuitable for use, this shall be reported to the customer	
outer that I said to be distantable for also, this shall be reported to the customer	

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and records maintained (see 4.2.4). NOTE Customer property can include intellectual property.	
7.5.5 Preservation of product	
The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection.  Preservation shall also apply to the constituent parts of a product.	PR15-16, PR17-19, , PR20-21, PR 26-28
7.6 Control of monitoring and measuring devices The organization shall determine the monitoring and measurement to be	N/A
undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1). The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.  Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended	This is applicable for validation activities that rely on experiments and associated test equipment; excluded for software development w/o measurement instruments
application shall be confirmed. This shall be undertaken prior to initial use and	
reconfirmed as necessary.  8 Measurement, analysis and improvement	
8.1 General	
The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed	Each phase contains a set of metrics to assess conformity of product.
a) to demonstrate conformity of the product,	PR26-28
b) to ensure conformity of the quality management system, and	Table 1, PR1
c) to continually improve the effectiveness of the quality management system.	Table 1, PR1, PR3-5
This shall include determination of applicable methods, including statistical	
techniques, and the extent of their use.	
8.2 Monitoring and measurement	
<b>8.2.1 Customer satisfaction</b> As one of the measurements of the performance of the quality management	PR6, PR7, PR23, PR25
system, the organization shall monitor information relating to customer	1 KO, 1 K/, 1 K23, 1 K23
perception as to whether the organization has met customer requirements. The	
methods for obtaining and using this information shall be determined.	
8.2.2 Internal audit	
The organization shall conduct internal audits at planned intervals to determine	
whether the quality management system	
a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements	Table 1, PR1, PR28, section 5

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established by the organization, and b) is effectively implemented and maintained. An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see	Table 1, PR1, PR28, section 5
8.5.2).  8.2.3 Monitoring and measurement of processes  The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	Table 1, PR1, PR3-5, section 5
8.2.4 Monitoring and measurement of product  The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).  Evidence of conformity with the acceptance criteria shall be maintained.  Records shall indicate the person(s) authorizing release of product (see 4.2.4).  Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.	PR26-28, PR1, PR7-8, PR17- 19, PR20-22
8.3 Control of nonconforming product  The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.  The organization shall deal with nonconforming product by one or more of the following ways:  a) by taking action to eliminate the detected nonconformity;  b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;  c) by taking action to preclude its original intended use or application.  Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).  When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.	PR13-16, PR26-28, PR17-19 PR1, PR11, PR13, , PR7-8, PR23 PR13-16, PR26-28, PR17-19
8.4 Analysis of data The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) customer satisfaction (see 8.2.1),	Section 5 PR23, PR25

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b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and	PR1, PR6-8, PR26-28 PR3-5
d) suppliers.	PR15, PR16
8.5 Improvement	
<b>8.5.1 Continual improvement</b> The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	Table 1, PR1-5, PR12, PR28, section 5
8.5.2 Corrective action  The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.  A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken.	PR5, PR12, PR17-19, PR25, PR28, section 5
8.5.3 Preventive action  The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.  A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing preventive action taken.	PR5, PR12, PR17-19, PR26-28, section 5

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